

Kot 3539

JAN 17 2007

SECTION 5
510(k) SUMMARY

510(k) Summary
NordicIceMedical AS
Nordic Image Control and Evaluation (nICE) Software

1. COMPANY NAME AND ADDRESS

1.1 Sponsor

NordicIceMedical AS
Mollendalsvein 61A
5008 Bergen
Norway
Telephone: +47 55389977
Fax: +47 55389971

Primary Contact: Tormod Thomsen (tormod@nordicneurolab.com)

Please be advised that effective December 1, 2006, NordicIceMedical AS will change its name to NordicImagingLab AS.

2. DEVICE NAME

Proprietary Name:	Nordic Image Control and Evaluation (nICE) Software
Common/Usual Name:	PACS
Device	System, image processing, radiological
Classification Name:	Picture archiving and communication system
Product Code	LLZ
21 VFR Regulation	892.2050

3. PREDICATE DEVICE

eFILM Workstation with Modules, K020995, Merge eMED, Inc.

4. DEVICE DESCRIPTION

Nordic Image Control and Evaluation (nICE) Software is a medical imaging manipulation tool, designed to provide a way to optimize the clinician's workflow. It targets activities fundamental to their work: reading, defining, sharing and reporting medical radiographic images. It is designed to work within a Windows™ operating system, and provides the user with the ability to view a wide range of image types.

5. INTENDED USE

Nordic Image Control and Evaluation (nICE) Software is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is used with general purpose computing hardware to acquire, transmit, process and store images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The nICE Software is substantially equivalent to the eFILM Workstation with Modules (K020995) in intended use, indications for use, technological characteristics and operational characteristics.

7. PERFORMANCE TESTING

Prospectively defined verification and validation activities for the nICE Software assure that the nICE Software is substantially equivalent to the cleared eFILM Workstation with Modules and meets design and performance specifications as well as user needs when operated according to the operating instructions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NordicIceMedical AS
% Mr. James W. Knox
Senior Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

JAN 17 2007

Re: K063539
Trade/Device Name: Nordic Image Control and Evaluation (nICE) Software version 2.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 22, 2006
Received: November 27, 2006

Dear Mr. Knox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

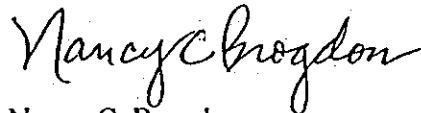
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150

or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 0 6 3 5 3 9

Device Name: Nordic Image Control and Evaluation (nICE) Software version 2.1

Indications For Use:

Nordic Image Control and Evaluation (nICE) Software is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is used with general purpose computing hardware to acquire, transmit, process and store images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K 0 6 3 5 3 9